REMARKS

I. Status of Claims

With this amendment, claims 1 and 2 are pending in the present application and under examination. Claims 22 and 23 are canceled. Claims 3-21 and 24-82 are withdrawn as being drawn to non-elected inventions.

Claim 1 has been amended to recite "outputting the identified amino acid sequence to a user display or to a computer readable media." Support for these amendments can be found throughout the specification, *e.g.*, at page 7, seventh paragraph, and page 8, first three paragraphs. By way of example, page 8, third paragraph, cites various common algorithms or programs for ORF identification. These identify ORFs by first scanning the entire sequence for initiation codons and then scanning sequences downstream of the initiation codon for in-frame termination codons. Once the ORFs have been identified, these programs have as an inherent step of outputting the identified amino acid sequence that one of skill in the art would recognize is the final step of these programs. Salzberg *et al.* (1998) *Nucl Acids Res* 26:544-548 has been previously provided in a supplemental information disclosure statement. Salzberg *et al.* discuss the program system GLIMMER disclosed on page 8, paragraph 3 of the specification. Salzberg *et al.* on page 547, col. 1, paragraph 2 indicate that, "[t]he final output of the program is a list of putative gene coordinates in the genome, together with notations for each one that may have has a suspicious overlap with another gene candidate." One of skill in the art would also recognize that the form of output varies from program to program. For example, some programs output the results by displaying on a screen, and other programs output by saving to computer readable media. Thus, Applicants assert that there is adequate support in the specification for these amendments and that no new matter has been added.

Cancellation and amendment of the claims is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications hereof containing the canceled or unamended claims.

II. Rejection of Claims Under 35 U.S.C § 101

Claims 1 and 2 have been rejected under 35 U.S.C. § 101 as allegedly being directed to nonpatentable subject matter. Specifically, the Examiner asserts that the claims may not output a tangible result.

This rejection and its supporting remarks are respectfully traversed. However, in the interest of advancing prosecution, without disclaimer or dedication to the public, applicants have amended the claims without actually changing the scope or interpretation at all by introducing "to a user display or to a computer readable media" so the tangible output that was implied by "outputting" is now expressly stated.

In view of the above remarks, Applicants respectfully request that this rejection be withdrawn.

III. Rejections under 35 U.S.C. § 103

Claims 1-2 have been rejected under 35 §103(a) as being unpatentable over Ribot et al. The Examiner admits that Ribot fails to teach all of the limitations of the claimed invention, but asserts that the differences between Ribot et al. should not be given any patentable weight. The Examiner has further Applicant respectfully traverses this rejection and its supporting remarks.

Specifically, the Examiner has asserted that the difference between the claimed invention and Ribot et al. "constitutes non-functional descriptive material because the content of the nucleic acid sequence database does not alter how the computer system functions, i.e., the database of the claimed computer system does not reconfigure the computer system to perform a different function than the computer system of Ribot et al."

As part of the burden to establish a *prima facie* case of obviousness on the grounds that claimed printed matter lacks patentable weight, the PTO must establish the absence of a novel, nonobvious functional relationship between the printed matter and the rest of the claimed invention. *See In re Lowry,* 32 U.S.P.Q.2d 1031, 1034 (Fed. Cir. 1994). In making his rejection, the Examiner

only cites four cases referenced in MPEP §2106.01 relating to utility rejections for printed matter or computer-related inventions, none of which support this assertion.

First, *In re Ngai* is not applicable to the presently pending claims. The claims at issue in *In re Ngai* were not process claims as asserted by the Examiner. The claim at issue was a composition claim. The Federal Circuit stated:

> This case, however, is dissimilar from *Gulack*. There the printed matter and the circularity of the band were interrelated, so as to produce a new ***product*** useful for "educational and recreational mathematical" purposes. Here, addition of a new set of instructions into a known ***kit*** does not interrelate with the ***kit*** in the same way as the numbers interrelated with the band. In *Gulack*, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result. Here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. All that the printed matter does is teach a new use for an existing product. As the *Gulack* court pointed out, "where the printed matter is not functionally related to the ***substrate***, the printed matter will not distinguish the invention from the prior art in terms of patentability." *Id.* If we were to adopt Ngai's position, anyone could continue patenting a ***product*** indefinitely provided that they add a new instruction sheet to the ***product***. This was not envisioned by Gulack. ***Ngai is entitled to patent his invention of a new RNA extraction method, and the claims covering that invention were properly allowed.*** He is not, however, entitled to patent a known product by simply attaching a set of instructions to that product. (emphasis added) *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004).

The Federal Circuit was correct in stating that the instructions and the kit were not functionally interrelated because they were two physical components of a composition. An infringing kit sold with the instructions could be used to practice the prior art method thereby not using the instructions at all because there was no functional relationship within the claim relating the instructions and the kit. It was not a method claim, so there was no requirement that the instructions be used as a part of the claimed composition. The kit was a box with components that could be used by one of skill in the art to practice any of a number of methods without ever using the instructions. Thus, there was no functional relationship between the instructions and the rest of

the claimed kit. On the other hand, the Federal Circuit held that the method claim was patentable. Thus this case really came down to whether it was proper to attempt to patent a new use by patenting a composition which is a kit with new instructions. This is utterly unrelated to the present claims as the present claims are method claims and the SEQ ID NO: 1 is functionally part of the claim and interrelates to the steps of the claims since the steps must be performed upon SEQ ID NO:1 which produces very different results from Ribot *et al.*

In re Lowry is also unrelated as the case involved composition claims to a memory for storing data.

In re Gulack is similarly unrelated as the case again involved composition claims to a device with printing upon the device.

The only case cited by the Examiner that touches upon claims to methods is *Diamond v. Diehr*. This case is also the most analogous to the pending claims. In Diamond, the patentee included a mathematical formula in the method claims where the mathematical formula (the Arrhenius equation) was used in a step of the claim to produce a useful result. Similarly, SEQ ID NO: 1 is used in the claim to produce the useful result – the amino acid sequence. Because the SEQ ID NO:1 is necessarily used in the practice of the claim given that it is a method claim, SEQ ID NO: 1 is necessarily legally functional in the claim.

Furthermore, the claim as amended requires that a database with the genome sequence of *N. meningitidis* serogroup B strain MC58. Ribot fails to provide the entire genome and therefore is not a method of identifying an amino acid sequence from the genome as is presently claimed.

Thus, the Examiner has failed establish a *prima facie* case that content of the sequence in the database lacks patentable weight. As the requirement that a *prima facie* case for obviousness establish that a reference or references combined must teach of suggest all of the limitations of the art was not disturbed by the recent Supreme Court *KSR Int'l Co. v Teleflex, Inc.* decision and as admitted by the Examiner, Ribot lacks this feature, Applicant therefore respectfully submits that the

Examiner has failed to make a *prima facie* case for obviousness. Withdrawal of the rejection is thus respectfully requested.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 223002100400. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: March 26, 2008

Respectfully submitted,

By /Otis Littlefield/

Otis Littlefield
Registration No.: 48,751
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, California 94105-2482
(415) 268-6846